A phase I/II study of human placental hematopoietic stem cell derived natural killer cells (CYNK-001) for the treatment of adults with COVID-19

Grant Award Details

A phase I/II study of human placental hematopoietic stem cell derived natural killer cells (CYNK-001) for the treatment of adults with COVID-19

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2COVID19-11857

Project Objective: Primary objective of this Phase I/II clinical study is to evaluate the safety, tolerability and efficacy of human placental hematopoietic stem cell derived NK cells (CYNK-001) in the treatment of adults with COVID-19

Investigator:

Name:	Xiaokui Zhang
Institution:	Celularity Inc
Type:	PI

Disease Focus: COVID-19, Infectious Disease, Respiratory Disorders

Human Stem Cell Use: Adult Stem Cell

Award Value: $750,000

Status: Active

Grant Application Details

Application Title: A phase I/II study of human placental hematopoietic stem cell derived natural killer cells (CYNK-001) for the treatment of adults with COVID-19

Public Abstract:

Therapeutic Candidate or Device

Human placental hematopoietic stem cell derived natural killer cells (CYNK-001)

Indication

SARS-CoV-2 positive patients requiring hospital admission and have any 2 out of 3 symptoms: fever, cough, or positive disease-related chest x-ray.

Therapeutic Mechanism

CYNK-001 is allogenic, human placental hematopoietic stem cell-derived NK cells that express the dominant NK cells marker CD56 and lack lineage markers such as CD3, and CD19. CYNK-001 demonstrates a range of biological activities expected of NK cells, it can recognize and kill the stressed and/or virus-infected cells. With demonstrated safety data from in vivo and clinical study, it is concluded that CYNK-001 is the potential cellular therapy for COVID-19 treatment.

Unmet Medical Need

The primary objectives of the Phase I study is to evaluate the safety, tolerability, and efficacy of CYNK-001 in COVID-19. The co-primary endpoints of Phase II study: A) To determine virologic efficacy of CYNK-001 in COVID-19 by rRT-PCR. B) To assess the impact of CYNK-001 on clinical symptoms.

Project Objective

Complete enrolling 86 patient for phase I/II study

Major Proposed Activities

- Complete phase I study for 14 COVID-19 patients enrollment
- Complete phase II study for 72 COVID-19 patients enrollment
- Clinical data record, collection and management

Statement of Benefit to California:

Provide potential stem cell based cellular therapeutic treatment for pandemic COVID-19, which will benefit not only for the State of California and its citizens, but for the people worldwide.

Source URL: https://www.cirm.ca.gov/our-progress/awards/phase-iii-study-human-placental-hematopoietic-stem-cell-derived-natural-killer